

### **REMARKS/ARGUMENTS**

In response to the Examiner's informality objection, Claims 8 - 12 have been amended to remove the underlining. Applicants very much appreciate the time and thought that the Examiner has taken to consider Applicants' responses. Applicants still believe that the present invention meets the criteria set by 35 U.S.C § 112, first paragraph and 35 U.S.C. § 101 even within the interpretation of the patent laws promulgated by the USPTO. In this spirit, Applicants respond as follows.

#### **Examiner's Action:**

The Examiner has maintained the rejection of claims 1, 2, 5, 6, and 7 under 35 U.S.C § 112, first paragraph and 35 U.S.C. § 101. In addition the Examiner has rejected new claims 8 - 12 on the same grounds under 35 U.S.C § 112, first paragraph and 35 U.S.C. § 101. When analyzing the claims under both statutory provisions, the Examiner states that:

"The claims are drawn to molecules, or sets of molecules, which result from a selection through a particular computer-implemented invention. No physical characteristics of the selected molecules or set of molecules are delineated by the claims.

Under 35 U.S.C § 112, first paragraph, the Examiner continues:

"No specific molecules or classes or sets of molecules are disclosed in the specification.....The claims are a wish to encompass molecules which may in the future be determined by Applicant's method. The selection method does not lead to the identification of a well known class of compounds or molecules.

Under 35 U.S.C. § 101, the Examiner continues:

“Molecules that are not identified have no specific, substantial or credible utility.

Molecules that are not identified have no well-established utility, as no one knows what the encompassed molecules are.”

**Applicants' Response:**

As noted by the Examiner, Applicants understand that they have not specified the selected molecules in a traditional manner such as by identification of a well known class of compounds or molecules. In traditional prior art approaches some non-three dimensional feature of compounds has been used to identify them as belonging to and being members of a set or class. But assignment to a specific feature class is not absolutely required under the patent laws. In the case where no common identifying element is readily or easily distinguished, patent law has evolved the Markush approach. In the present circumstance, Applicants have developed a new and validated criteria by which to distinguish a set or class of molecules. That criteria is by the overall three dimensional shape of the molecules.

The power of this method of classification is that molecules having chemically different structures (in the traditional 2-D molecular/chemical sense) and/or derived from chemically different synthetic pathways (different chemistries) may be identified and recognized as being members of a unique set based on their similar three dimensional shape. This is a new type of classification, but it is as valid a way to classify molecules as any method in the prior art. In fact, by its very nature “physical characteristics of the selected molecules or set of molecules are

delineated.”

Applicants added claims 8 – 12 in their last response in an attempt to highlight this feature of a class definition. The claims to the “set” of molecules either possessing no common 3-D shape or possessing a common 3-D shape define classes (sets) of molecules as surely as the traditional 2-D approaches well established in the art. Applicants submit that this is a subtle but crucial point which is emphasized by the claim to a “set.” The set defines the class. It is not a traditional 2-D classification, but rather a new 3-D classification. It can encompass molecules from different chemistries and 2-D structures, the only requirement being that the molecules in the set either: 1) do not share the same 3-D shape; or 2) share the same 3-D shape which is also the shape of a molecule of interest.

In pharmaceutical development terms, the second case is particularly important since the members of the set may contain other molecules based on the same chemistry as the lead molecule which also have the desired biological activity, OR may contain other molecules derived from an entirely different chemistry as the lead molecule which also have the desired biological activity. The second case is usually termed a “lead hop” and may be crucial when medicinal chemical modification of the lead fails to increase its desirability as a drug. A lead hop may also be important to avoid a previously patented (2-D) chemical area.

Applicants incorporate in this Response Applicants’ remarks in response to the prior office actions, and respectfully request the Examiner to review those remarks again in light of the further arguments presented above. Applicants submit that the disclosure and claims meet the written description requirements of 35 U.S.C § 112, first paragraph since the characteristics

of specific classes of molecules are specified, including the physical characteristics (similarity of three dimensional structure) which define a set. Applicants also respectfully submit that the disclosure and claims meet the requirements of 35 U.S.C. § 101 since a specific, substantial and credible utility has been asserted. Applicants submit that the characteristic of the sets of molecules have been identified and that it is the commonality or non-commonality of three dimensional structure, not particular 2-D style chemical structure, that can be assigned to the sets of encompassed molecules. By itself, even without the other elements of utility asserted by Applicants, this criteria for classifying molecules provides the utility required by the statute.

Applicants note that the Examiner has not repeated the 35 U.S.C. 35 § 102(e) rejection based upon Agrafiotis et al. and, therefore, conclude that Applicants' traverse in the prior office action response was accepted by the Examiner.

Applicants respectfully submit that they have addressed and provided adequate responses to all the grounds of rejection raised by the Examiner, and Applicants respectfully request that the Examiner remove the rejections of record and issue a timely Notice of Allowance.

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Respectfully submitted,



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